2017 Updated Recommendations on the Use of Chlorhexidine-Impregnated Dressings for Prevention of Intravascular Catheter-Related Infections

Centers for Disease Control and Prevention
National Center for Zoonotic and Emerging Infectious Diseases
Division of Healthcare Quality Promotion


a Vanderbilt University School of Medicine, Vanderbilt University Medical Center, b Division of Healthcare Quality Promotion, National Center for Emerging and Zoonotic Infectious Diseases, Centers for Disease Control and Prevention, c Northrop Grumman Corporation, d Time Solutions LLC, and e Contributing HICPAC Members

Suggested citation:
Centers for Disease Control and Prevention. 2017 Recommendations on use of chlorhexidine-impregnated dressings for prevention of intravascular catheter-related infections: An update to the 2011 guidelines for the prevention of intravascular catheter-related infections from the Centers for Disease Control and Prevention. Centers for Disease Control and Prevention, National Center for Emerging and Zoonotic Infectious Diseases, Division of Healthcare Quality and Promotion. DATE. (DHQP website URL to be added)

Disclosures and disclaimers:
The authors report no actual or potential conflicts of interest related to the commercial products discussed herein. This document is not protected by the Copyright Act, and copyright ownership cannot be transferred. It may be used and reprinted without special permission.
### Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>BSI</td>
<td>bloodstream infection</td>
</tr>
<tr>
<td>CABSI</td>
<td>catheter-associated bloodstream infection</td>
</tr>
<tr>
<td>CDC</td>
<td>Centers for Disease Control and Prevention</td>
</tr>
<tr>
<td>CHG</td>
<td>chlorhexidine gluconate</td>
</tr>
<tr>
<td>C-I</td>
<td>chlorhexidine-impregnated</td>
</tr>
<tr>
<td>CLABSI</td>
<td>central line-associated bloodstream infection</td>
</tr>
<tr>
<td>CMS</td>
<td>Centers for Medicare &amp; Medicaid Services</td>
</tr>
<tr>
<td>CRBSI</td>
<td>catheter-related bloodstream infection</td>
</tr>
<tr>
<td>CRI</td>
<td>catheter-related infections</td>
</tr>
<tr>
<td>CVC</td>
<td>central venous catheter</td>
</tr>
<tr>
<td>FDA</td>
<td>U.S. Food and Drug Administration</td>
</tr>
<tr>
<td>GRADE</td>
<td>Grading of Recommendations Assessment, Development and Evaluation</td>
</tr>
<tr>
<td>HICPAC</td>
<td>Healthcare Infection Control Practices Advisory Committee</td>
</tr>
<tr>
<td>ICU</td>
<td>intensive care unit</td>
</tr>
<tr>
<td>IV</td>
<td>intravenous</td>
</tr>
<tr>
<td>MSB</td>
<td>maximal sterile barrier precautions</td>
</tr>
<tr>
<td>NICU</td>
<td>neonatal intensive care unit</td>
</tr>
<tr>
<td>PICU</td>
<td>pediatric intensive care unit</td>
</tr>
<tr>
<td>PCICU</td>
<td>pediatric cardiac intensive care unit</td>
</tr>
<tr>
<td>RCT</td>
<td>randomized controlled trial</td>
</tr>
<tr>
<td>SR</td>
<td>systematic review</td>
</tr>
</tbody>
</table>
Updated Recommendations on the Use of Chlorhexidine-Impregnated Dressings for Prevention of Intravascular Catheter-Related Infections (2017)

Table of Contents
Abbreviations .............................................................................................................................................................2
Table of Contents .......................................................................................................................................................3
List of Tables and Figures ........................................................................................................................................3
1.0 Summary ..............................................................................................................................................................4
   1.1 Recommendations ...........................................................................................................................................4
2.0 Background ..........................................................................................................................................................5
3.0 Methods ................................................................................................................................................................5
   Figure 1: Yield of Systematic Search of Articles Published January 2010–March 2017 ...................................6
   Table 1. Categorization Scheme for Recommendations21,22 ...................................................................................7
4.0 Evidence Summary ...............................................................................................................................................7
   4.1 Patients Aged 18 Years and Older ................................................................................................................7
      4.1.1 Dressings and skin antisepsis ....................................................................................................................7
      4.1.2 Catheter-related bloodstream infection .....................................................................................................8
      4.1.3 Catheter-related infection ..........................................................................................................................8
      4.1.4 Product-related adverse events ..................................................................................................................8
      4.1.5 Chlorhexidine resistance............................................................................................................................8
      4.1.6 Limitations of the evidence .......................................................................................................................9
   4.2 Patients Younger Than 18 Years ....................................................................................................................10
      4.2.1 Dressings and skin antisepsis ..................................................................................................................10
      4.2.2 Catheter-related bloodstream infection ...................................................................................................10
      4.2.3 Catheter-associated bloodstream infection ..............................................................................................10
      4.2.4 Bloodstream infection without a source ..................................................................................................11
      4.2.5 Local catheter infection ...........................................................................................................................11
      4.2.6 Product-related adverse events ................................................................................................................11
      4.2.7 Chlorhexidine resistance..........................................................................................................................11
      4.2.8 Limitations of the evidence .....................................................................................................................11
5.0 Implementation Considerations for Patients aged 18 Years and Older ..............................................................12
6.0 References ..........................................................................................................................................................13
Contributors ..............................................................................................................................................................15
   Staff and contractors of the Centers for Disease Control and Prevention ............................................................15
   Healthcare Infection Control Practices Advisory Committee (HICPAC) ............................................................15

List of Tables and Figures
Tables:
   Table 1: Categorization Scheme for Recommendations

Figures:
   Figure 1: Yield of Systematic Search of Articles Published January 2010–March 2017
1.0 Summary

In 2011, the Centers for Disease Control and Prevention (CDC) and CDC’s Healthcare Infection Control Practices Advisory Committee (HICPAC) issued Guidelines for the Prevention of Intravascular Catheter-Related Infections. This document (hereafter called the 2011 Guidelines) included two recommendations about the use of chlorhexidine-impregnated (C-I) dressings, along with other strategies included in multicomponent interventions (“bundles”) to prevent intravascular catheter-related infections. By 2017, additional evidence had emerged regarding the benefits and harms of one or more of these types of dressings for use with intravenous (IV) catheters, central venous catheters (CVCs), and arterial catheters. The U.S. Food and Drug Administration (FDA) has cleared C-I dressings based on bench testing data, demonstrating effectiveness of the device as a barrier to bacterial penetration to the catheter site, and the effectiveness of chlorhexidine in the reduction of bioburden within the dressing during use. The FDA has cleared a subset of these dressings with the specific indication for preventing catheter-related bloodstream infection (CRBSI) based on results from clinical testing data.

This document provides evidence-based recommendations on the use of C-I dressings that update selected recommendations from the 2011 Guidelines. These recommendations are based on: 1) a systematic review of literature published in English from January 1, 2010 through March 6, 2017; 2) a systematic grading of the quality of evidence (Appendix Table 4 and Appendix Table 5); 3) input from infection prevention experts at CDC and HICPAC; and 4) input from the public. Prior to finalizing the recommendations, CDC solicited input from HICPAC and the public on the draft recommendations, reviewed these comments, incorporated relevant changes, and sought final HICPAC input at a public teleconference on May 5, 2017, during which HICPAC unanimously voted to approve the updated recommendations.

1.1 Recommendations

1. For patients aged 18 years and older:
   a. Chlorhexidine-impregnated dressings with an FDA-cleared label that specifies a clinical indication for reducing catheter-related bloodstream infection (CRBSI) or catheter-associated blood stream infection (CABSI) are recommended to protect the insertion site of short-term, non-tunneled central venous catheters. (Category IA)
   (See Section 5.0 Implementation Considerations for Patients Aged 18 Years and Older).

2. For patients younger than 18 years:
   a. Chlorhexidine-impregnated dressings are NOT recommended to protect the site of short-term, non-tunneled central venous catheters for premature neonates due to risk of serious adverse skin reactions. (Category IC)
   b. No recommendation can be made about the use of chlorhexidine-impregnated dressings to protect the site of short-term, non-tunneled central venous catheters for pediatric patients less than 18 years old and non-premature neonates due to the lack of sufficient evidence from published, high-quality studies about efficacy and safety in this age group. (unresolved issue)

These recommendations supersede only the two statements about C-I dressings in the section on Catheter Site Dressing Regimens (Recommendations 12 and 13) in the 2011 Guidelines.

The updated recommendations on use of C-I dressings for short-term, non-tunneled CVCs do not supersede other recommendations about tunneled CVCs, peripheral intravenous catheters, arterial catheters, and other topics covered in the 2011 Guidelines.
2.0 Background

In 2011, CDC and HICPAC released *Guidelines for the Prevention of Intravascular Catheter-Related Infections* that included two recommendations for C-I dressings:

- Use a chlorhexidine-impregnated sponge dressing for temporary short-term catheters in patients older than 2 months of age if the central line-associated bloodstream infection (CLABSI) rate is not decreasing despite adherence to basic prevention measures, including education and training, appropriate use of chlorhexidine for skin antisepsis, and maximal sterile barrier precautions (MSB) (Category 1B: defined in 2011 as strongly recommended for implementation and supported by some experimental, clinical, or epidemiologic studies and a strong theoretical rationale; or an accepted practice [e.g., aseptic technique] supported by limited evidence).

- No recommendation is made for other types of chlorhexidine dressings (unresolved issue: defined in 2011 as represents an unresolved issue for which evidence is insufficient or no consensus regarding efficacy exists).

The 2011 recommendations were based on published evidence from the date of the first indexed article in the database through December 2009. The evidence consisted of randomized controlled trials (RCTs) and systematic reviews (SRs) that examined C-I sponge dressings, but not other types of C-I dressings. Between January 2010 and March 2017, new evidence accrued, including:

1. two RCTs that examined C-I sponge dressings or C-I gel dressings
2. two meta-analyses of these two types of C-I dressings evaluated as a single product class
3. a professional association’s compendium of strategies for the prevention of CLABSI (CDC experts participated in the development of this document, which contains a section that evaluated two different C-I dressings as a single product class).

3.0 Methods

CDC developed the following key question using the PICO (Patient, Intervention, Comparator, Outcome) format to guide the search of published literature on C-I dressings in adults (defined as patients aged 18 years and older) and children (defined as patients younger than 18 years).

Does use of C-I dressings, compared with use of standard dressings, affect the risk of intravascular infections associated with short-term, non-tunneled central venous catheters in adults and children?

CDC conducted a systematic review of the best available evidence on C-I dressings. CDC then used a modification of the Grading of Recommendations Assessment, Development and Evaluation (GRADE) method to assess the quality of the available evidence, to determine the strength of recommendations, and to show the relation between evidence and recommendations.

Two reviewers (Dasti, Overholt) systematically searched articles indexed in MEDLINE and the Cochrane Library for articles published through March 6, 2017 (Appendix Table 1, Appendix Table 2, and Appendix Table 3). Two reviewers (Overholt, Stone) screened article titles and abstracts and retrieved full text articles if they were:

1. relevant to the key question;
2. randomized controlled trials, systematic reviews, or meta-analyses;
3. written in English; and
4. available as full-text studies (excluding published meeting abstracts).

These reviewers also reviewed the full-text articles and excluded articles that were:

1. conducted in dialysis settings, and
2. not RCTs (Figure 1).
Disagreements were resolved by discussion.

For studies that met the inclusion criteria, two reviewers (Overholt, Stone) extracted data on: the study author, year, study design, objective, population, intervention, outcome definitions, intervention and control events, hazard ratios, confidence intervals, and p-values. Reviewers contacted authors of selected studies to confirm the skin antisepsis agent and use of daily chlorhexidine bathing if these details were not reported in the article. They extracted data as originally presented in the articles and resolved discrepancies through discussion. Two reviewers (Overholt, Stone) assessed the risk of bias for each RCT using an index developed by the University of Pennsylvania Health System’s Center for Evidence-Based Practice, as had been used for recent CDC and HICPAC guidelines (Appendix Table 8 and Appendix Table 9).

**Figure 1: Yield of Systematic Search of Articles Published January 2010–March 6, 2017**

The guideline writing group (comprised experts in infection control and evidence-based guideline development; listed as authors) reviewed the findings from the evidence review and formulated recommendations based on the balance of benefits and harms of C-I dressings when used for preventing infections associated with short-term, non-tunneled catheters. The strength of each recommendation was based on the categorization scheme used for previous CDC healthcare infection control guidelines (Table 1). The writing group did not consider the following issues when formulating recommendations: cost or cost-effectiveness of C-I dressings in healthcare facilities with different underlying rates of catheter use or catheter-related infections; dressing preferences of providers or health systems; provider opinions about ease of dressing application, removal, or inspection for complications; or the
impact of dressing use on other aspects of catheter care (e.g., frequency of dressing change, compatibility with catheter materials).

Table 1. Categorization Scheme for Recommendations\textsuperscript{21,22}

<table>
<thead>
<tr>
<th>Category</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td>IA</td>
<td>A strong recommendation supported by high-to-moderate quality evidence suggesting net clinical benefits or harms.</td>
</tr>
<tr>
<td>IB</td>
<td>A strong recommendation supported by low-quality evidence suggesting net clinical benefits or harms, or an accepted practice (e.g., aseptic technique) supported by low-to-very low-quality evidence.</td>
</tr>
<tr>
<td>IC</td>
<td>A strong recommendation required by state or federal regulation.</td>
</tr>
<tr>
<td>II</td>
<td>A weak recommendation supported by any quality of evidence suggesting a tradeoff between clinical benefits and harms.</td>
</tr>
<tr>
<td>No recommendation/unresolved issue</td>
<td>An unresolved issue for which there is either low-to-very low-quality evidence with uncertain tradeoffs between benefits and harms or no published evidence on outcomes deemed critical to weighing the risks and benefits of a given intervention.</td>
</tr>
</tbody>
</table>

Other sources describe additional details of the guideline development process.\textsuperscript{21,22}

4.0 Evidence Summary

4.1 Patients Aged 18 Years and Older

Five RCTs addressed one or more types of intravascular catheter-related infections in this age group (Appendix Table 4).\textsuperscript{8-12} CDC classified the following infection outcomes as critical for decision-making: CRBSI and catheter-related infections (CRI). Product-related adverse events and chlorhexidine resistance were considered important outcomes. The results of the five studies were not directly comparable because they differed regarding the following conditions that might influence rates of intravascular catheter-related infections and product-related adverse events: skin antiseptic agents used before catheter insertion and during catheter maintenance, catheter type and insertion site, use of silver sulfadiazine-chlorhexidine-impregnated catheters, clinical outcome definitions, other components of CLABSI prevention bundles, frequency of dressing changes, hospital unit, and severity and types of health conditions of study participants.

The authors of four\textsuperscript{8-12} of the five RCTs reported receiving funds and/or materials from, and/or being employed by, the manufacturer of the C-I dressing under study.

4.1.1 Dressings and skin antisepsis

One of the five RCTs compared transparent C-I gel dressings\textsuperscript{11} with highly adhesive transparent dressings or with standard, breathable, hypoallergenic dressings. Four studies compared C-I sponges covered by transparent adhesive dressings with transparent adhesive dressings alone.\textsuperscript{8-10,12} Each of these four studies specified that the transparent adhesive dressing and skin antisepsis methods were the same in the intervention groups and control groups. However, descriptions of the transparent adhesive dressings varied by study, including: transparent, semipermeable, polyurethane, occlusive dressing;\textsuperscript{8} semipermeable, transparent dressing;\textsuperscript{12} standard, sterile, transparent wound dressing;\textsuperscript{10} or occlusive dressing.\textsuperscript{9} Whether these different dressings (hereafter called “standard dressings”) affect the risk of intravascular catheter-related infection is unknown. The skin cleaning and skin antisepsis agents and methods used before catheter insertion and during catheter maintenance also varied by study. One RCT used alcohol spray,\textsuperscript{10} one RCT used aqueous povidone-iodine,\textsuperscript{8} one RCT used alcoholic
povidone-iodine, one RCT used alcoholic chlorhexidine, and one multicenter RCT used alcoholic chlorhexidine or alcoholic povidone-iodine depending on the facility’s standard of care (Appendix Table 6).

4.1.2 Catheter-related bloodstream infection

High-quality evidence suggested a benefit of using C-I dressings to reduce the rate of CRBSI. This was based on four RCTs, all rated at low risk of bias. Reductions in rates of CRBSI were found in three RCTs evaluating C-I sponge dressings and one RCT evaluating C-I gel dressings. The three larger trials compared C-I gel dressings with highly adhesive or standard dressings, and C-I sponge dressings with standard dressings (Appendix Table 4). One of the studies was stopped early due to observed benefit of the C-I sponge dressing. A fourth smaller RCT evaluating the efficacy of C-I sponge dressings found no difference in CRBSI rates by dressing type. This study was stopped early due to low enrollment. Two of the large RCTs enrolled patients receiving central venous and arterial catheters to achieve adequate study power. One of these RCTs conducted subanalyses by catheter type and found a significant reduction in CRBSI rates among patients with CVCs, but found no difference in CRBSI rates among patients with arterial catheters (Appendix Table 6).

4.1.3 Catheter-related infection

Moderate-quality evidence suggested a benefit to using C-I dressings to reduce the rate of CRI. This was based on four RCTs, rated at moderate and low risk of bias, that compared C-I gel dressings with highly adhesive and standard dressings, or C-I sponge dressings with standard dressings (Appendix Table 4). The two larger studies found a reduction in CRI when using C-I gel dressings compared with highly adhesive or standard dressings, and when using C-I sponge dressings compared with standard dressings. In order to achieve adequate study power, these two RCTs enrolled patients with CVC and/or arterial catheters. One of these studies conducted subanalyses by catheter type and found a significant reduction in CRI rates among patients with CVCs, but not among patients with arterial catheters. Two smaller studies with lower study power found no difference in the incidence of CRI by dressing type (Appendix Table 6).

4.1.4 Product-related adverse events

Moderate-quality evidence suggested that the use of C-I dressings was associated with an increase in the incidence of product-related adverse events. Two large RCTs found no incidence of systemic adverse events to C-I dressings in patients with either C-I sponge dressings or C-I gel dressings. Four RCTs evaluated contact dermatitis and local redness in patients with either C-I sponge dressings or C-I gel dressings versus patients with standard dressings alone (Appendix Table 4). All studies were rated at low risk of bias. Definitions of contact dermatitis varied by study, but all addressed reactions near the catheter insertion site (Appendix Table 6). Two large studies assessed adverse events using a standard rating system and found that use of either C-I sponge dressings or C-I gel dressings was associated with significantly higher rates of severe contact dermatitis (requiring dressing removal) or local redness as compared with standard dressings. Two studies found no product-related adverse events. Two studies found no incidence of systemic adverse reactions.

4.1.5 Chlorhexidine resistance

Low-quality evidence from two RCTs that compared C-I sponge dressings with standard dressings suggested no difference by dressing type in measures of resistance to chlorhexidine in bacteria isolated from skin, CVCs, or blood cultures (Appendix Table 4). These RCTs assessed patients who underwent skin antisepsis with alcohol spray or alcoholic povidone-iodine (Appendix Table 6). Both studies were rated at low risk of bias. These studies were not directly comparable because standard methods to measure bacterial resistance to chlorhexidine are not available and each study used different methods to measure resistance.
4.1.6 Limitations of the evidence

The body of evidence for patients aged 18 years and older is limited by the factors noted above and by the following issues:

- The best available evidence published between 1998 and March 2017 that assessed the clinical outcomes of CRBSI and CRI consisted of RCTs evaluating only two types of C-I dressings. During this interval, the chlorhexidine concentration and the materials and properties of these C-I dressings may have changed.

- Three\(^8,10,12\) of the five evaluated studies did not use insertion site skin antisepsis methods such as alcoholic chlorhexidine recommended for CVCs by the 2011 Guidelines.\(^1\) Only two\(^9,11\) of the five RCTs evaluated patients who underwent chlorhexidine skin antisepsis before catheter insertion. One of these studies\(^11\) found that use of C-I dressings significantly reduced intravascular catheter-related infections as compared with standard dressings, and the other, possibly underpowered study\(^9\) found no difference. Whether the benefits of C-I dressings over standard dressings would be observed or achieve the same magnitude if skin antisepsis with alcoholic chlorhexidine were used for all patients is unclear.

- None of the studies evaluated the effect of chlorhexidine skin antisepsis in combination with C-I dressings on systemic reactions to chlorhexidine. There are increased reports of anaphylactic reactions to chlorhexidine skin preparations\(^23\). These reports raise questions about how C-I dressings may impact the effect of chlorhexidine skin preparation on anaphylactic reactions. Due to this uncertainty, surveillance should continue to monitor any possible association between use of C-I dressings and chlorhexidine skin antisepsis to determine if there is an increasing association with anaphylactic reactions. As stated in the FDA Safety Announcement on this topic: “Health care professionals should always ask patients if they have ever had an allergic reaction to any antiseptic before recommending or prescribing a chlorhexidine gluconate product. Advise patients to seek immediate medical attention if they experience any symptoms of an allergic reaction when using the products. Consider using alternative antiseptics such as povidone-iodine, alcohols, benzalkonium chloride, benzethonium chloride, or parachlorometaxylenol (PCMX) when any previous allergy to chlorhexidine gluconate is documented or suspected.”

- None of the studies evaluated patients who were uniformly bathed with 2% chlorhexidine. One study\(^8\) followed patients in five intensive care units (ICUs), (one of which contributed approximately 40% of study subjects) used both daily CHG bathing and C-I dressings. For this reason, the combined effect of CHG bathing and C-I dressings on CRBSI rates remains uncertain.

- None of the studies directly compared rates of intravascular catheter-related infections or product-related adverse events in patients with C-I sponge dressings versus patients with C-I gel dressings.

- All studies reported low incidence of infections and adverse events and minor differences in incidence between study groups. These minor differences may be difficult to detect in studies with limited study power or in clinical settings without highly sensitive surveillance for these infections. However, the infection rate at which use of C-I dressings would be cost-saving or cost-effective would vary by the cost of diagnosing and treating intravascular catheter-related infections, dressings, and other measures to prevent intravascular catheter-related infections in a given facility. Nevertheless, even a slight increase in infection rates may prompt health care facilities to introduce prevention strategies in order to improve patient health outcomes and satisfaction.

- The studies had limited power to detect chlorhexidine resistance associated with C-I dressings. Little is known about the influence of temporary C-I dressings on chlorhexidine resistance and the protective microbiome of human skin, or the impact of using multiple chlorhexidine-based interventions (e.g., C-I dressings, CHG skin preparation, and CHG bathing) on risk of chlorhexidine resistance. Studies describe associations between chlorhexidine products and clinical isolates with reduced susceptibility to chlorhexidine or other antimicrobials (i.e., colistin) or identified chlorhexidine resistance mechanisms (e.g., resistance genes and plasmid-mediated resistance).\(^24-29\) These reports raise questions about how
emerging resistance may affect the balance of benefits and harms of using C-I dressings to prevent intravascular catheter-related infections. Given this uncertainty, surveillance and research should continue to assess the association between use of C-I dressings and resistance to chlorhexidine or other antimicrobials and to determine if emerging resistance might reduce the benefits of using C-I dressings to prevent intravascular catheter-related infections.

4.2 Patients Younger Than 18 Years

Three RCTs addressed one or more types of intravascular catheter-related infections in this age group (Appendix Table 5). CDC classified the following outcomes as critical for decision-making: CRBSI, catheter-associated bloodstream infection (CABSI), bloodstream infection (BSI) without a source, and local catheter infection. CDC classified chlorhexidine resistance and product-related adverse events as important outcomes. The results of the three studies were not directly comparable because they differed regarding the following conditions that might influence rates of intravascular catheter-related infections and product-related adverse events: skin antiseptic agents used before catheter insertion and during catheter maintenance, frequency of dressing changes, catheter type and insertion site, clinical outcome definitions, and severity and types of health conditions of study participants.

The authors of one RCT reported receiving funds from the manufacturer of the C-I dressing used in the study.

4.2.1 Dressings and skin antisepsis

Two studies compared outcomes among patients with C-I sponges covered by transparent polyurethane dressings with outcomes among patients with transparent polyurethane dressings alone (hereafter called “standard dressings”). The third study compared a C-I gel dressing with a sterile gauze pad. Skin cleaning methods and antiseptic agents used before catheter insertion and catheter dressing change protocols varied by study (Appendix Table 7).

4.2.2 Catheter-related bloodstream infection

Very low-quality evidence from two RCTs suggested no difference in the incidence of CRBSI by dressing type (Appendix Table 5). The first RCT of neonatal intensive care unit (NICU) patients with a mean gestational age of 30.9 weeks in the C-I group vs. 30.7 weeks in the control group compared C-I sponge dressings applied after skin antisepsis with 70% isopropyl alcohol with standard dressings applied after skin antisepsis with 10% povidone-iodine. This study, rated at moderate risk of bias, found that rates of CRBSI did not differ by dressing type. However, this RCT had low study power because enrollment was stopped early due to low rates of CRBSI and funding issues (Appendix Table 7). The second RCT of pediatric intensive care unit (PICU) patients aged 1 month to 18 years compared C-I gel dressings with sterile gauze pads after skin antisepsis with 10% povidone-iodine (Appendix Table 5). This study, rated at moderate risk of bias, found that rates of CRBSI did not differ by dressing type (Appendix Table 7).

4.2.3 Catheter-associated bloodstream infection

Low-quality evidence from one RCT suggested no difference in the incidence of CABSI by dressing type (Appendix Table 5). This small RCT compared C-I sponge dressings with standard dressings alone in pediatric cardiac ICU (PCICU) patients aged from birth to 18 years (mean age 21 to 31 months) who underwent skin antisepsis with chlorhexidine solution. This study was rated at moderate risk of bias. Rates of CABSI did not significantly differ by dressing type (Appendix Table 7).
4.2.4 Bloodstream infection without a source

Very low-quality evidence from one RCT suggested no difference in the incidence of BSI without a source by dressing type (Appendix Table 5). This RCT in NICU patients compared C-I sponge dressings applied after skin antisepsis with 70% isopropyl alcohol with standard dressings alone applied after skin antisepsis with 10% povidone-iodine. This study, rated at moderate risk of bias, found that rates of BSI without a source did not differ by dressing type (Appendix Table 7).

4.2.5 Local catheter infection

Low-quality evidence from one RCT suggested no difference in the incidence of local catheter infections by dressing type (Appendix Table 5). This RCT in PICU patients compared C-I gel dressings with sterile gauze pads. This study, rated at moderate risk of bias, suggested no statistically significant difference in the incidence of local catheter infection per patient by dressing type (Appendix Table 7).

4.2.6 Product-related adverse events

Moderate-quality evidence from two RCTs suggested that use of C-I dressings was associated with an increase in severe product-related adverse events (Appendix Table 5). One RCT with NICU patients found severe and/or localized contact dermatitis developed in 5.7% of neonates with C-I sponge dressings and none of the control neonates with standard dressings. The incidence of severe and/or localized contact dermatitis among neonates using C-I sponge dressings was substantially higher (15%) among neonates who weighed ≤ 1,000 grams than among neonates who weighed 1,000 grams or more (1.5%). Two neonates developed pressure ulcers from the C-I sponge and two other neonates developed scars from severe contact dermatitis. Many of the dressings in affected neonates were placed on or before the eighth day of life. The second, smaller RCT of PCICU patients younger than 18 years reported local redness in four neonates with C-I sponge dressings and one neonate with a standard dressing. Neonates with redness did not require dressing changes or CVC removal, and redness spontaneously resolved after catheter removal in all cases. The study did not report the weights and ages of the four neonates with C-I dressings. Both studies were rated at moderate risk of bias (Appendix Table 7).

4.2.7 Chlorhexidine resistance

None of the studies addressed this outcome.

4.2.8 Limitations of the evidence

The three studies were limited by the factors noted above and these additional issues:

- None of the studies reported rates of clinical infection outcomes by patient age.
- All three studies reported few infections and so were statistically underpowered to detect differences in outcomes by dressing type. Additionally, the rates of CRBSI in the NICU study and the PICU study were not stratified by gestational age or infant weight; this precluded assessment of clinical outcomes by infant age and weight.
- One study used different agents for skin antisepsis before dressing application in the two arms: alcohol spray in the intervention arm and aqueous povidone-iodine in the control arm. These differences precluded direct assessment of the outcomes by dressing type.
- The duration of catheter placement differed by study. The PCICU study reported a mean of 4.7 days for catheters protected with C-I dressings, and a mean of 4.4 days for catheters protected with standard dressings. The PICU study reported a mean of 13.78 days for children with C-I dressings and 14.24 days for children with standard dressings. In the largest study of NICU patients, catheters were in place longer: a mean of 17.7 days for catheters protected with C-I dressings and a mean of 17.4 days for
catheters protected with standard dressings. The potential effect of duration of catheter placement on infection outcomes and severe contact dermatitis limits the comparability of these studies.

5.0 Implementation Considerations for Patients aged 18 Years and Older

Select insertion site dressings based on the needs of the patient. Several factors affect both the choice of dressings for patients aged 18 years and older and the decision to add specific dressings to existing CLABSI prevention bundles. These include, but are not limited to, the interval since catheter insertion, insertion site (e.g., bleeding or oozing), physical and chemical compatibility of the dressing with catheter components, patient sensitivity to dressings, and facility procurement and supply management. There are now three different dressings recommended for use with short-term, non-tunneled CVCs in patients < 18 years of age, including the updated recommendations in this report and other recommendations in the 2011 Guidelines\textsuperscript{1} that were not addressed by this update. Most studies of C-I dressings did not use other CDC-recommended interventions that have become routine practice or part of CLABSI prevention bundles (such as use of alcoholic chlorhexidine for skin preparation). Whether study effect sizes would have been of the same magnitude if these routine practices had been used is unclear. To date, evidence is insufficient to define the elements of the optimal CLABSI prevention bundle or which bundle components, when used in combination, would measurably reduce the rate of infections while minimizing complications.

Every healthcare facility in the United States that uses CVCs should track CLABSI outcomes and process measures to identify opportunities to prevent patient harm. Facilities should ensure high adherence to existing CLABSI prevention policies, practices, and bundles using regular audit and feedback and other means, regardless of which type of dressing is chosen. In healthcare settings that are demonstrating success at preventing CLABSI, the addition of C-I dressings is optional.
6.0 References


Contributors

Staff and contractors of the Centers for Disease Control and Prevention

Scientific advice: Michael Bell, MD, Jeffrey Hageman, MHS, L. Clifford McDonald, MD

Editorial, Information Science, and Graphical Support: Sonya Arundar, MS; Srila Sen, MA; Rose Pecoraro

Healthcare Infection Control Practices Advisory Committee (HICPAC)

- **HICPAC Members**: Hilary M. Babcock, MD, MPH, Washington University School of Medicine, St. Louis, MO; Vickie M. Brown, RN, MPH, WakeMed Health and Hospitals, Raleigh, NC; Sheri Chernenks Tejedor, MD, Emory University School of Medicine, Atlanta, GA; Daniel J. Diekema, MD, University of Iowa Carver College of Medicine, Iowa City, IA; Susan Huang, MD, MPH, University of California, Irvine School of Medicine; Loretta L. Fauerbach, MS, CIC, Fauerbach and Associates, LLC, Gainesville, FL; Michael D. Howell, MD, MPH, The University of Chicago Medicine, Chicago, IL; W. Charles Huskins, MD, MSc, Mayo Clinic College of Medicine, Rochester, MN; Lynn Janssen MS, CIC, CPHQ, California Department of Public Health, Sacramento, CA; Lisa L. Maragakis, MD, MPH, Johns Hopkins Hospital, Baltimore, MD; Jan Patterson, MD, University of Texas Health Science Center at San Antonio, TX; Gina Pugliese, RN, MS, Premier Healthcare Alliance, Charlotte, NC; Selwyn O. Rogers Jr., MD, MPH, FACS, University of Texas Medical Branch, Galveston, TX; Tom Talbot, MD, MPH, Vanderbilt University Medical Center, Nashville, TN; Michael L. Tapper, MD, Lenox Hill Hospital, New York, NY; Deborah S. Yokoe, MD, MPH, Brigham and Women's Hospital, Boston, MA.

- **Ex Officio Members**: William B. Baine, MD, Agency for Healthcare Research and Quality, Rockville, MD; David Henderson, MD, National Institutes of Health, Bethesda, MD; Melissa Miller, MD, Agency for Healthcare Research and Quality, Rockville, MD; Paul D. Moore, PhD, Health Resources and Services Administration, Rockville, MD; Elizabeth Claverie-Williams, MS, U.S. Food and Drug Administration, Silver Spring, MD; Sheila Murphey, MD, U.S. Food and Drug Administration, Silver Spring, MD; Gary Roselle, MD, Cincinnati Department of Veterans Affairs (VA) Medical Center, Cincinnati, OH; Daniel Schwartz, MD, MBA, Centers for Medicare and Medicaid Services, Baltimore, MD; Jacqueline Taylor, Health Resources and Service Administration, Rockville, MD; Judy Trawick, Health Resources and Service Administration, Rockville, MD.